Remarks

Reconsideration of the application in view of the above amendments and the following remarks is requested.

Claims 1-10 are pending. Claims 1, 5, 9 and 10 have been amended to include only pharmaceutically acceptable salts, enantiomers, diastereomers, N-oxides and polymorphs. Claims 1 and 3 have also been amended to remove overlap with Korgaonkar et al. Claim 3 has been amended to separate the compounds by semicolons. Claims 4 and 7 have been cancelled. Claims 9 and 10 have been amended to recite specific reactants and reaction conditions. Support for the amendment made to claim 9 is found, for example, on page 11, lines 4-8 and Scheme I. Support for the amendment made to claim 10 is found, for example, on page 12, lines 4-7 and Scheme II. No new matter is introduced thereby.

Rejection Under 35 U.S.C. §112, Second Paragraph

Claims 1-10 have been rejected as indefinite for reciting "amides", "prodrugs" and "metabolites" in claims 1, 4, 5, 9 and 10 (and claims dependent therefrom). Claims 4 and 7 have been rejected as indefinite for not specifying the medical condition and claims 9 and 10 have been rejected as indefinite for not setting forth the reactants and reaction conditions. Applicants respectfully traverse the rejection for the following reasons.

Claims 1, 5, 9 and 10 have been amended to remove the terms "amides", "prodrugs" and "metabolites".

The indefiniteness of claims 4 and 7 has been mooted by deletion of the claims.

Claims 9 and 10 have been amended to include specific reactants and reaction conditions as the Examiner has suggested.

Applicants respectfully submit that the instant rejections have been overcome by applicants' amendments to the claims, and that the rejection should be reconsidered and withdrawn.

Rejection Under 35 U.S.C. §102(b) Over Korgaonkar (J.Ind.Chem.Soc., v. LX, (1983) 874-876)

Claims 1-4, 6, 7 and 9 have been rejected as anticipated by Korgaonkar. Applicants respectfully traverse the rejection for the following reasons.

As presented herein, claims 1, 3, 6 and 9 are not anticipated by Korgaonkar et al. Korgaonkar discloses certain aryl piperazinyl tetrahydrophthalimides as CNS depressants, including methods of making such compounds. See Korgaonkar et al., structure XI, p. 874, and compounds XIa-g listed in Table 1, p. 875. The substituents which are disclosed as being present in the aryl ring portion of the tetrahydrophthalimides are H, 2-, 3-, and 4-CH_3, and 2-, 3-, and 4-Cl.

Applicants believe that claims as presented herein are not anticipated by Korgaonkar et al. Claims 1 and 3 as amended include compounds which are different from the compounds disclosed in Korgaonkar et al. The compounds of the present invention were specifically designed as highly selective and safe α_1-AR antagonists specifically for use in BPH. The compounds of the present invention were found to possess α_1-AR antagonist selectivity which could then be used for treating BPH without causing vascular side effects, whereas nowhere does Korgaonkar et al., disclose or suggest α_1-AR selectivity.

The structural differences between the compounds of the present invention and Korgaonkar et al. have been found to result in extremely high selectivity. Since the compounds of the present invention are novel and not anticipated by Korgaonkar et al., the claims which depend from either claim 1 or 3 are also not anticipated.

Claim 9 as amended claims process for the preparation of novel compounds. Since the compounds of the present invention are novel and not anticipated by Korgaonkar et al., the process to prepare the novel compounds is also not anticipated.

Applicants respectfully submit that the claimed invention is not anticipated by Korgaonkar, and request reconsideration and withdrawal of the rejection.

Rejection Under 35 U.S.C. §103(a) Over Ishizumi et al. (United States Patent No. 4,598,078 or Chem. Pharm. Bull., v. 39(9), (1991) 2288-2300)

Claims 1-3, 6, 8 and 9 have been rejected as obvious over Ishizumi et al. Applicants respectfully traverse the rejection for the following reasons.

Claims 1, 3, 6, 8 and 9 as presented herein are unobvious over Ishizumi et al. As is well known, to establish a prima facie case of obviousness, three criteria must be met. First, there must be motivation in the prior art references to modify the reference. Second, there must be a reasonable expectation of success and third, the prior art reference must teach or suggest all the claimed limitations. In this connection, all the teachings and suggestions as well as the expectation of success must come from the prior art and not from the applicants' disclosure.

There is no suggestion in Ishizumi et al. of the desirability of modifying the reactions disclosed in these references to obtain the novel compounds for the high α_1-AR selectivity for use in BPH disclosed in the present invention. Further, it is clear that neither problem nor solution is discernible to one with ordinary skill in the art from the teachings of prior art references. Applicants respectfully request reconsideration and withdrawal of the rejections.

Applicants submit that the claims are supported by the disclosure as filed, and respectfully request reconsideration and withdrawal of the rejection. This would overcome all outstanding rejections and result in allowable claims.

Conclusion

Applicants respectfully submit that the pending claims are allowable, and request a Notice of Allowance at this time. Authorization is hereby given to charge any fees deemed to be due in connection with this Response to Deposit Account No. 50-0912.

Respectfully submitted,

ANAND *et al.*

By: _____

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